Claim Rejections

The Examiner rejected claims 1-6, 8-12, 23-27 and 29-31 under 35 U.S.C. § 102(b) as being anticipated by DeCrosta (U.S. Patent No. 4,666,705). The Examiner asserts that "DeCrosta et al. teach a tablet comprising an acrylic polymer and lubricants," and that carbopols are disclosed, as well as auxiliary hydrocolloids including mixtures of cellulose ethers and cellulose alkylhydroxylates, talc, magnesium stearate and lactose. Applicants respectfully disagree with the Examiner and offer the following rebuttal of the rejection.

DeCrosta discloses a controlled release tablet formulation of angiotensin converting enzyme inhibitor that includes 20-60% medicament, 50-80% acrylic acid polymer and 0.5-8% lubricant. Optionally, the formulation may include an auxilliary hydrocolloid gelling agent (column 4, lines 56-66).

The present invention is directed to a pharmaceutical device or composition that comprises about 1 to less than 50% by weight covalently crosslinked water insoluble, water swellable polymers and about 1 to 75% by weight uncrosslinked, linear water soluble polymers. The Applicant's have found that the unique combination of these two recited elements provide for a controlled, sustained release of the pharmaceutical incorporated therein when administered and ingested within the GI tract. DeCrosta does not teach or suggest such a composition and its ranges and thus cannot anticipate the noted claims.

Reconsideration and withdrawal of the rejection of claims 1-6, 8-12, 23-27 and 29-31 under 35 U.S.C. § 102(b) as being anticipated by DeCrosta (U.S. Patent No. 4,666,705) is respectfully requested.

The Examiner also rejected claims 7 and 28 under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of DeCrosta and Tsujino (U.S. Patent No. 3,789,117). Applicants respectfully traverse this rejection.

The DeCrosta reference is discussed *supra*. Tsujino teaches a process for the preparation of enteric medicaments in which cellulose esters as enteric coats are disclosed. The combination of these two references does not provide or suggest the presently claimed invention. DeCrosta is deficient in teaching a required combination of covalently crosslinked water insoluble, water-swellable polymers and uncrosslinked, linear water soluble polymers. As stated in DeCrosta, the hydrocolloid gelling agent is optional. Thus, DeCrosta teaches away from the required combination as presently claimed. Therefore, simply adding the coating teaching of Tsujino does not provide or suggest the claimed combination which is essential to the invention and provides for the characteristic of controlled delivery of the pharmaceutical contained therein.

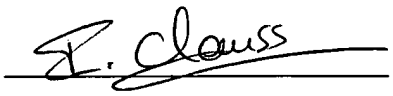
Reconsideration and withdrawal of the rejection of claims 7 and 28 under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of DeCrosta and Tsujino (U.S. Patent No. 3,789,117) is respectfully requested.

Conclusion

For the reasons given above, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Applicants submit that the pending claims are in condition for allowance.

Respectfully submitted,

FOLEY, HOAG & ELOIT



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Copy of amended claims showing changes relative to the previous version of the claims, as required under 37 C.F.R. § 1.121(c):

1. (Amended) A controlled release pharmaceutical delivery device which provides sustained or pulsatile delivery of a selected pharmaceutically active substance for a predetermined period of time, said device comprising;

- about 1 to less than 50% by weight covalently crosslinked water insoluble, water-swellable polymers;
- about 1 to 75% by weight uncrosslinked, linear water soluble polymers.

9. (Amended) A controlled release pharmaceutical delivery device which provides sustained or pulsatile delivery of a selected pharmaceutically active substance for a predetermined period of time, said device comprising;

- about 1 to less than 50% [60%] by weight of a mixture of hydroxyethylcellulose[;] and [- about 1 to 75% by weight of]hydroxypropylmethyl cellulose;
- about 1 to 60% by weight of ethylcellulose;
- about 1 to 80% by weight of at least one Carbopol® resin;
- about less than 10% by weight of talc;
- about less than 10% by weight of magnesium stearate; and
- about less than 95% by weight granulating and tableting aids.

23. (Amended) A pharmaceutical composition comprising;

- about 1 to 80% by weight pharmaceutically active agent;
- about 1 to less than 50%[80%] by weight covalently crosslinked water insoluble water swellable polymers; and
- about 1 to 75% by weight uncrosslinked, linear water soluble polymers.

30. (Amended) A pharmaceutical composition comprising :

- about 1 to 80% pharmaceutically active agent;
- about 1 to 60% by weight of hydroxyethylcellulose;
- about 1 to 75% by weight of hydroxypropylmethyl cellulose;
- about 1 to 60% by weight of ethylcellulose;

- about 1 to less than 50% [80%] by weight of at least one Carbopol® resin;
- about less than 10% by weight of talc;
- about less than 10% by weight of magnesium stearate; and
- about less than 95% by weight granulating and tableting aids.